Home Monitoring of Lung Function (eICE-ID-10)

Summary

This study evaluated whether at-home monitoring of lung function and symptoms could improve lung function after 12 months by providing earlier detection and treatment of exacerbations. Study participants were randomly assigned to one of two groups: 1) home monitoring, in which spirometry and respiratory symptoms were recorded twice weekly or 2) usual care. For participants in the home monitoring group, the spirometry and symptom information was transmitted by phone modem weekly to the study nurse; if the data indicated a possible pulmonary exacerbation, participants were prescribed treatment. Participants in the usual care group contacted their clinic if they were feeling sick and their physician would determine if treatment was needed.

Specimen Information

Status: Specimens are Available

For each subject enrolled in this study a specimen for banking is collected at baseline (subject in a stable non-exacerbated state) and a second sample is collected when the subject returns to the clinic for an acute visit at the start of an excerbation. As such the timing between samples is variable but will be reflected in the table below as 3 months.

Visit #	Time From Baseline	Specimens Collected
1	+0 Days	EDTA plasma, Serum
2	+3 Months	EDTA plasma, Serum

Study Design

Study Type?	Interventional
Randomized Study?	Yes
Placebo Controlled?	No
Length of Participation	1 Years
Number of Study Visits?	7

Additional Information

Phase?	Not Applicable
Study Sponsor?	Goss, Christopher
Study Drugs?	N/A

Eligibility

Age	14 Years and Older
Mutation(s)	No Mutation Requirement
FEV1% Predicated	26 % or greater
PA Status	Not Applicable
Other	Eligible subjects are in a clinically stable state at baseline.

Study Results

WHAT WE LEARNED:

Study results showed that after 12 months there was no difference in lung function between the home monitoring group when compared to the usual care group.

PRIMARY FINDINGS:

EFFECTIVENESS:

This multi-center study was conducted between October 2011 and July 2015. The study enrolled 267 participants, 135 were randomized to the home monitoring group and 132 to the usual care group. The study was stopped early by the Data Monitoring Committee due to no clear differences being observed between the home monitoring and usual care groups (futility) and lagging enrollment. The primary analysis results showed no difference in lung function (mean change in FEV1 after 52 weeks) in the home monitoring group compared with the usual care group.

SAFETY:

A higher rate of hospitalizations for pulmonary exacerbations was observed in the home monitoring group compared to usual care (Rate Ratio=1.45, 95% C.I. = [1.09, 1.93], p=0.01). This higher rate of hospitalization was expected, since the intervention was designed to detect respiratory complications more rapidly than usual care.

CITATION:

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For more information about the results of this study and where it was conducted, visit ClinicalTrials.gov.